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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	NO. 1:19-cv-3040-SAB DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' CROSS MOTIONS FOR SUMMARY JUDGMENT February 13, 2019 1:15 p.m. Courtroom 755

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION, FEMINIST WOMEN'S HEALTH CENTER, DEBORAH OYER, M.D., and TERESA GALL, F.N.P.,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as United States Secretary of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANE FOLEY, M.D., in her official capacity as Deputy Assistant Secretary for Population Affairs, and OFFICE OF POPULATION AFFAIRS,

Defendants.

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INTRODUCTION[1]

In *Rust v. Sullivan*, 500 U.S. 173 (1991), the Supreme Court held that Department of Health and Human Services (HHS) regulations (1988 regulations) prohibiting Title X projects from referring patients for abortion as a method of family planning, and requiring Title X programs to be physically separate from abortion-related activities, were authorized by Title X, were not arbitrary and capricious, and were constitutional. Relying on that holding, HHS issued a new rule in 2019 that is, in all material respects, indistinguishable from the 1988 regulations. *See* 84 Fed. Reg. 7714 (Mar. 4, 2019) (Rule). Notwithstanding *Rust*'s holding, Plaintiffs bring this suit asserting that the current Rule, *inter alia*, violates Title X, is arbitrary and capricious, and violates the Constitution. As Defendants explained in their opening brief and, earlier, in opposition to Plaintiffs' motion for a preliminary injunction, these claims fail and the Court should enter summary judgment for Defendants. *See* Defs.' Mem. in Supp. of Mot. to Dismiss & for

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[1] This memorandum exceeds the page limit set forth in Civil Rule 7(f). On January 10, 2020, Defendants filed an unopposed motion to expand the page limits for this memorandum. ECF No. 130. Defendants recognize that the timing of the motion to expand the page limits did not give the Court time to rule before Defendants filed this memorandum, and Defendants' apologize to the Court. Defendants respectfully renew their request for leave to exceed the page limit in Civil Rule 7(f).

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Summ. J. (Defs.' MSJ), ECF No. 112; Defs' Mem. in Opp'n to Pls.' Mot. for Prelim. Inj. (Defs.' PI Opp'n), ECF No. 44.

In their most recent briefs, *see* State of Wash. Opp'n to Defs.' Mot. to Defs.' Mot. to Dismiss and for Summ. J. & Cross Mot. for Summ. J. (Wash. MSJ), ECF No. 118; Nat'l Family Planning & Reproductive Health Ass'n Plaintiffs' Opp'n to Defs.' Mot. to Dismiss & for Summ. J & Cross-Mot. for Summ J. (NFPRHA MSJ), ECF No. 121, Plaintiffs double down on the remarkable arguments they asserted when seeking a preliminary injunction: that this Court can effectively overrule a Supreme Court decision based on a single clause in an appropriations rider, an obscure provision in the Affordable Care Act (ACA), or later Supreme Court cases *reaffirming* the decision; and that the Court can substitute its judgment for the predictive expertise of the agency charged with administering the Title X program. As set forth below and in Defendants' opening brief, Plaintiffs' arguments fail, and the Court should enter summary judgment for Defendants on all claims asserted in Plaintiffs' complaints.

Plaintiffs also spend many pages—and, indeed, the bulk of their combined 150 pages of briefing—in an ultimately futile attempt to demonstrate that HHS acted arbitrarily and capriciously, and Plaintiffs have combed the record to cite commenters who supported their position during the rulemaking process. But the length of Plaintiffs' briefs does not make their arguments stronger, nor make it any more acceptable, as Plaintiffs appear to believe, for this Court to "substitute its judgment for that of the agency." *Peck v. Thomas*, 697 F.3d 767, 772 (9th Cir.

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2012). It is black letter law that courts are not permitted to do so under the Administrative Procedure Act (APA). Because HHS provided a reasoned justification for the regulations it adopted over the objections of Plaintiffs (and some other commenters), and made reasonable predictions using its expertise, Plaintiffs' arbitrary-and-capricious claims fail. Plaintiffs fare no better in arguing that certain aspects of the Rule are not logical outgrowths of HHS's proposals in the NPRM, as Plaintiffs received sufficient notice to meaningfully comment on the substance of the Rule as promulgated.

Finally, Plaintiffs barely defend their constitutional claims, and suggest that the Court need not reach them. Understandably so, as these claims lack merit for the simple reason that they are foreclosed by *Rust*, which already held that materially indistinguishable regulations do not violate the Constitution under the theories that Plaintiffs pursue here.

I. PLAINTIFFS' STATUTORY CLAIMS LACK MERIT

Plaintiffs continue to press the argument that the Rule violates Title X itself and two later-enacted statutory provisions. But as Defendants have explained, the Supreme Court has held that Title X authorizes materially indistinguishable regulations. Plaintiffs' attempt to show that this authorization has been silently repealed is inconsistent with the text of the relevant statutes and fails to meet the high standard necessary to overcome the presumption against implied repeals.

A. The Nondirective Provision

Title X plainly authorizes the Rule's restrictions on referrals and counseling. If a program refers patients for, or otherwise promotes, abortion as a method of family planning, then the program is one "where abortion is a method of family planning" and, hence, ineligible for funding under § 1008. 42 U.S.C. § 300a-6; *see* 84 Fed. Reg. at 7759. Plaintiffs suggest that § 1008 merely prohibits "funding abortion," Wash. MSJ at 6, but even the 2000 regulations concluded that is "not . . . the better reading." 65 Fed. Reg. 41,270, 41,272 (July 3, 2000) (preamble). After all, when Congress wants to prevent only the funding of abortion, it knows how to do so. *See* Pub. L. No. 96-123, § 109, 93 Stat. 923, 926 (1979) ("[N]one of the funds provided by this joint resolution shall be used to perform abortions."). Section 1008, by contrast, reveals "Congress' intent in Title X that federal funds not be used to 'promote or advocate' abortion as a 'method of family planning.'" *Rust*, 500 U.S. at 195 n.4.

All of this remains true notwithstanding a subsequent appropriations rider providing that Title X funds "shall not be expended for abortions" and that "all pregnancy counseling shall be nondirective." Pub. L. No. 115-245, div. B., tit. II, 132 Stat. 2981, 3070-71 (2018). If anything, that rider reinforces § 1008 by further ensuring that pregnancy counseling is not used to "direct" patients *toward* abortion. Plaintiffs' contrary arguments do not withstand scrutiny.

1. Plaintiffs' primary argument is that the Rule's restrictions on abortion referrals are directive (in violation of the appropriations rider) when combined with the separate requirement that pregnant patients be referred for

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prenatal health care. *See* Wash. MSJ at 46-48. But the prenatal-referral requirement does not direct a decision about abortion—it merely refers women for care while they are pregnant, even if they obtain an abortion later. *See* Defs.' MSJ at 20. And the Rule permits providers to explain that abortion is outside the scope of the program, and that if a patient wants to seek an abortion, she can find information about that elsewhere. In the meantime, however, it permits providers to give the patient a list of providers who can offer her care while she is pregnant. *See* 42 C.F.R. § 59.14(e)(5). Providers could even include an express disclaimer that the prenatal-care referral is a general requirement and should not be taken as directing the patient's ultimate decision about her pregnancy. And even if the required prenatal-care referral were directive, that would not justify invalidating the prohibition on abortion referrals, which are contained in different subsections, 42 C.F.R. §§ 59.16(a), 59.16(b)(1), and, as Defendants have explained, are severable, Defs.' MSJ at 20 (citing 84 Fed. Reg. at 7725).

In any event, Congress's requirement that "pregnancy counseling" be "nondirective" does not speak to the issue of "referrals," much less require HHS to allow referrals for abortion specifically. Plaintiffs insist that in passing the appropriations rider, Congress must have intended "counseling" to refer to "referrals" as well, relying heavily on a separate statute's—the Infant Adoption Awareness Act, *see* Wash. MSJ at 47—use of those terms. But that statute just requires the Secretary to make grants to "adoption organizations for the purpose of developing and implementing programs to train the designated staff of eligible

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health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women." 42 U.S.C. § 246(a)(1). Plaintiffs read the statute as indicating that "referrals" are "inclu[ded] . . . *within* 'nondirective counseling," Wash. MSJ at 49, but the term "included" instead modifies the "other courses of action" potentially addressed in pregnancy counseling—namely, abortion or carrying to term. This statute has no bearing on whether Congress considers referrals a *type* of counseling (as opposed to something that may occur *at the same time* as counseling).

2. Plaintiffs' challenge to the Rule's counseling provisions fares no better. Given that the Rule *permits* "nondirective pregnancy counseling, which may discuss abortion," 42 C.F.R. § 59.14(e)(5), Plaintiffs focus on the fact that the Rule does not *require* counseling on abortion. Wash. MSJ at 51-52. But in providing that "all pregnancy counseling shall be nondirective, the appropriations rider does not require *any* pregnancy counseling at all—especially in a "*preconceptional* family planning program" such as Title X, *Rust*, 500 U.S. at 202. Nor does a provider's choice to omit counseling about abortion specifically "direct" anything. The Rule's preamble contemplates that any counseling will present more than one option, *see, e.g.*, 84 Fed. Reg. at 7716, and offering childbirth-only counseling or adoption-only counseling would not "direct" a patient to choose that option, so long as the provider did not advise a patient to do so. At most, such counseling would (implicitly) "promote" that option over the

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others, but nothing in the appropriations rider prohibits the promotion of childbirth or adoption. Section 1008, by contrast, does prohibit the use of Title X funds "to 'promote or advocate' abortion as a 'method of family planning,'" *Rust*, 500 U.S. at 195 n.4, which is why the Rule forbids counseling where "abortion [is] the only option presented," 84 Fed. Reg. at 7747.

In short, the Rule is consistent with the nondirective provision, and it is possible to give it effect while also (unlike Plaintiffs) giving effect to the interpretation of Title X (and specifically § 1008) upheld in *Rust*.[2]

3. Even if this were a closer question, settled interpretive principles would dispose of Plaintiffs' construction of the appropriations rider. Plaintiffs do not dispute that there is a heightened presumption against implied repeals through appropriations legislation, *see* Defs.' MSJ at 19, but contend that the presumption is inapplicable here. Yet they confirm that, under Plaintiffs' interpretation, the nondirective provision "narrowed" the agency's authority to interpret (and, thus,

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[2] Plaintiffs are thus incorrect in accusing Defendants of reading the nondirective provision to have "no legal effect." Wash. MSJ at 48; *see also id*. at 42-43. The Rule prohibits abortion referrals to individuals or entities outside of the Title X program, consistent with § 1008, while requiring, consistent with the text of the nondirective provision, that any pregnancy counseling that is provided within the Title X program (including counseling on abortion) be nondirective. *See* 84 Fed. Reg. at 7730.

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act pursuant to) § 1008. *See* Wash. MSJ at 45. By definition, that is a repeal of § 1008 in relevant respect. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 663 n.8 (2007) ("Every amendment of a statute effects a partial repeal to the extent that the new statutory command displaces earlier, inconsistent commands.").

If § 1008 explicitly delegated HHS authority "to prohibit Title X projects from referring their patients for abortion as a method of family planning," for instance, no one would dispute that subsequent legislation stripping the Department of that authority would constitute a repeal. That § 1008, combined with the express rulemaking authority granted under § 1006, *implicitly* delegated the same authority is irrelevant under *Chevron*. *See* Defs.' MSJ at 27-28. And that is especially true where the Supreme Court has already authoritatively construed § 1008 to contain that delegation, a scenario none of Plaintiffs' authorities address. *See* Antonin Scalia & Brian A. Garner, *Reading Law* 331 (2012) (noting that even when an "earlier ambiguous provision has already been construed by the jurisdiction's high court to have a meaning that does not fit as well with a later statute as another meaning," any "[l]egislative revision of law clearly established by judicial opinion ought to be by express language or by unavoidably implied contradiction").

B. Section 1554 of the ACA

1. Plaintiffs do not dispute that they failed to raise their argument based on § 1554 of the ACA before HHS during the rulemaking process. Rather, they

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ask the Court to excuse that waiver for a variety of reasons, none of them persuasive. It is not enough, as Plaintiffs contend, that commenters made generic objections to the substance of (as opposed to the statutory authorization for) the Rule containing language that happened to resemble language in § 1554. *See* Wash. MSJ at 56-57. Nor is it the case that the waiver doctrine is inapplicable to arguments regarding "statutory limitations" on an agency's "rulemaking authority." *Id*. at 55-56. Rather, as the D.C. Circuit has explained, "failure to raise a particular question of statutory construction before an agency constitutes waiver of the argument in court," notwithstanding the fact that a party raised other "technical, policy, or legal arguments before the agency," because "respect for agencies' proper role in the *Chevron* framework requires that the court be particularly careful to ensure that challenges to an agency's interpretation of its governing statute are first raised in the administrative forum." *NRDC, Inc. v. EPA*, 25 F.3d 1063, 1074 (D.C. Cir. 1994) (citations omitted); *see also Koretoff v. Vilsack*, 707 F.3d 394, 398 (D.C. Cir. 2013) (requiring a party to raise "specific argument" it presses in court before the agency, "not merely the same general legal issue"); Defs. MSJ at 29-30.[3] Plaintiffs do not argue that any of the

[3] For the same reasons, the fact that HHS listed the entire ACA as a source that it relied upon in promulgating the Rule, *see* Wash. MSJ at 54, does not mean that it considered the particular statutory argument that Washington is making here (but that was not raised in any comments)—*i.e.*, that the Rule violates the

comments it references actually invoked § 1554, or more importantly invoked that particular statutory provision as a legal bar to the Rule, and thus HHS had no "opportunity to consider the issue." *Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1024 (9th Cir. 2007).

Washington further argues that, because the Rule is currently in effect and "has been applied to Washington," it should now be permitted to raise any argument it wants, "irrespective of what arguments were raised during the notice-and-comment process." Wash. MSJ at 57. But although Washington misleadingly tries to suggest otherwise, the state's voluntary departure from the Title X program does not mean it was "subject to" an enforcement action, *id*., and this lawsuit is not, in fact, an as-applied challenge to a specific HHS action enforcing the Rule against Washington.[4] Rather, Washington contends, as it has

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obscure "Access to therapies" provision of that voluminous legislation—much less that Plaintiffs' waiver should be excused on that basis. *See Koretoff*, 707 F.3d at 398 ("[A]gencies have no obligation to anticipate every conceivable argument about why they might lack statutory authority.")

[4] Indeed, although the Rule has not been applied to Washington (which, again, chose to leave the Title X program on its own), HHS does employ enforcement proceedings with respect to Title X grants. These require, among other things, HHS to provide a grantee notice prior to terminating funding based on noncompliance with applicable regulations, 45 C.F.R. § 75.373, and "an

from the start, that the Rule is facially invalid based on its asserted conflict with certain statutory and constitutional requirements, and seeks an order setting the Rule aside in its entirety. The case law on which Defendants have previously relied—which simply recognizes that waiver doctrine does not prevent a party from raising an argument that it failed to make during agency rulemaking when the "rule is brought before [a] court for review of *further agency action applying it*," *i.e.*, action beyond mere promulgation of the rule itself, *Koretoff*, 707 F.3d at 399 (emphasis added) (quoting *Murphy Exploration & Prod. Co. v. U.S. Dep't of Interior*, 270 F.3d 957, 958 (D.C. Cir. 2001))—is thus inapplicable to this lawsuit. *Contra* Wash. MSJ at 57. Whether or not the Rule is currently in effect, it remains the case that "the price for a ticket to facial review is to raise objections in the rulemaking." *Koretoff*, 707 F.3d at 401 (Williams, J., concurring).

2. Waiver aside, Plaintiffs' § 1554 argument is meritless. The Rule merely limits what the government chooses to fund and thus does not, for example, "create[] any unreasonable barrier" to obtaining health care. 42 U.S.C. § 18114(1). As the Supreme Court explained in *Rust*, there is a fundamental distinction between impeding something and choosing not to subsidize it, 500 U.S. at 201-02; *see* Defs.' MSJ at 30, and that reasoning disposes of the issue, whether it is packaged as a constitutional or statutory claim.

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opportunity to object and provide information and documentation challenging the suspension or termination action," *id*. § 75.374.

In addition, while Plaintiffs dismiss the fact that § 1554 applies "[n]otwithstanding any other provision of this Act," 42 U.S.C. § 18114—thereby signaling that this provision may implicitly displace otherwise applicable provisions *only in the ACA* (*see* Wash. MSJ at 59-60)—they never explain why Congress used that language when it repeatedly used the common phrase "notwithstanding any other provision of law" elsewhere in the ACA. *See* Defs.' MSJ at 31-32. And none of Plaintiffs' various arguments make § 1554 any less of a mousehole or their theory any less of an elephant: "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions," *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001), and § 1554 qualifies as both. Nor do those arguments demonstrate a congressional intent, "manifest" or otherwise, to eliminate HHS's authority, recognized by the Supreme Court in *Rust*, to promulgate regulations materially indistinguishable from the current Rule. *See Nat'l Ass'n of Home Builders*, 551 U.S. at 662. Plaintiffs' § 1554 claim fails.[5]

C. Title X

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[5] As Defendants have explained, *see* Defs.' MSJ at 30-31, Plaintiffs interpretation of § 1554 would mean that HHS could not, for example, even adopt a regulation declining to provide Medicare coverage for any specific procedure, and would therefore halt HHS from making even minor changes to programs that it administers any time a provider or patient would be arguably adversely affected.

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The Rule likewise does not violate "Title X's central purpose," Wash. MSJ at 65, which is the same as it was the day the Supreme Court decided *Rust*. *Cf. Rust*, 500 U.S. at 188-89 (rejecting similar argument that the physical-separation requirement was inconsistent with Congress's "intent" to create "a comprehensive, integrated system of family planning services"). Nor does the Rule violate the provision of Title X—which Plaintiffs do not dispute was in place at the time *Rust* held that the "broad language of Title X plainly allows" the materially indistinguishable 1988 regulations—that "[t]he acceptance by an individual of family planning services or family planning or population growth information" provided through the Title X program "shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information." 42 U.S.C. § 300a-5. To the contrary, the Rule preserves a regulatory provision implementing this statutory directive. *See* 42 C.F.R. § 59.5(a)(2). Again, similar statutory arguments were advanced in *Rust* and the Supreme Court never accepted them. *See, e.g.*, Reply Brief for State Petitioners at 6-7, *Rust*, (Nos. 89-1391, 1392), 1990 WL 505761; *see also Rust*, 500 U.S. at 202 (rejecting constitutional argument that the 1988 regulations "interfere with a woman's right to make an informed and voluntary choice").

Plaintiffs also contend that 42 C.F.R. § 59.18 violates Title X by "limit[ing] the use of Title X funds for core functions," Wash. MSJ at 68, but fails to mention that this provision only forbids expenditures "*for purposes prohibited with these*

funds, such as support for the abortion business of a Title X grantee or subrecipient." 42 C.F.R. § 59.18(a) (emphasis added); *see also id*. § 59.18(b) (prohibiting use of funds for "activity . . . that in any way tends to promote public support or opposition to any legislative proposal or candidate for office"). Those restrictions are entirely consistent with § 1008.

Finally, Plaintiffs challenge the provision of the Rule that requires Title X projects to "offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site in order to promote holistic health and provide seamless care." 42 C.F.R. § 59.5(a)(12). Plaintiffs contend that such "comprehensive primary health services" fall "outside the scope of Title X," Wash. MSJ a 68-69. But as HHS explained in the Rule, this provision strikes an appropriate balance between focusing Title X funds on their core purpose—"preventive care and preconception family planning"—while also ensuring, through the promotion of "robust referral networks," that clients "have ready access to non-Title X health care services that they need, including treatment for health conditions that are not provided by Title X and for postconception care (other than abortion as a method of family planning)." 84 Fed. Reg. at 7733. It is curious for Plaintiffs to raise this argument—essentially, that HHS cannot tell Title X projects to refer for medical services outside the Title X program—when their argument regarding the nondirective provision hinges on the contention that HHS *must* require Title X projects to refer patients for abortion services

necessarily performed outside the Title X program. *See, e.g.*, Wash. MSJ at 8 (criticizing Rule for "striking previous requirement[] that patients be . . . referred for out-of-program care upon request"). In any event, Plaintiffs do not actually identify any specific provision of Title X with which this provision of the Rule is inconsistent, nor explain how the fact that the Rule requires Title X projects to have a system for providing referrals for necessary medical care outside the auspices of the program to patients who need it somehow undermines Title X.

Because *Rust* has already established that the Rule is consistent with Title X, and because the Rule does not, in any event, condition eligibility for other HHS programs on an individual's acceptance of Title X services, as § 300a-5 forbids, or otherwise run afoul of the statute, the Court should dismiss Plaintiffs' Title X claim.

II. THE RULE IS NOT ARBITRARY AND CAPRICIOUS

Plaintiffs have failed to demonstrate that the Rule is arbitrary and capricious. Plaintiffs' arguments are mere policy disagreements in the guise of APA claims, and their most recent briefs cover no new ground. Agency action must be upheld in the face of an arbitrary and capricious claim so long as the agency "examine[s] the relevant data and articulate[s] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). HHS did precisely that. While Plaintiffs

clearly disagree with the policy judgments contained in the Rule, they cannot show that HHS acted unlawfully.

A. The Referral and Counseling Restrictions Are Reasonable.

HHS reasonably adopted the prohibitions on promoting and referring for abortion because they implement the best reading of § 1008—namely, that a program that refers patients for, or promotes, abortion as a method of family planning is by definition a program "where abortion is a method of family planning." *See* 84 Fed. Reg. at 7759. The Supreme Court held in *Rust* that such "justifications are sufficient to support the Secretary's revised approach," 500 U.S. at 187, which is "plainly allow[ed]" by Title X, *id*. at 184. That conclusion remains true today, and HHS adequately explained its reasons for adopting the Rule. Plaintiffs' contrary arguments lack persuasive force.

First, NFPRHA asserts that HHS failed to explain what NFPRHA alleges is a departure from the 2000 regulations with respect to Defendants' interpretation of the nondirective provision. NFPRHA MSJ at 11-13, 15-18. But contrary to NFPRHA's claim, and as Defendants have explained, HHS never concluded in the 2000 regulations that the nondirective provision required suspension of the 1988 regulations. For HHS, the "crucial difference between" the 1988 regulations and the 2000 regulations was simply "one of experience." 65 Fed. Reg. 41,270, 41,271 (July 3, 2000) (2000 regulations). Thus, there was no reversal of position as to HHS's interpretation of the nondirective provision—which HHS continues to recognize requires that all pregnancy counseling that is offered be nondirective,

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see, e.g., 84 Fed. Reg. at 7733—and therefore no need for any additional explanation than what exists in the Rule's preamble. More generally, and contrary to NFPRHA's claim, HHS clearly acknowledged that the 2000 regulations required Title X projects to provide abortion referrals and nondirective counseling on abortion, and HHS explained at length the reasons for the changes in the Rule. *See* 84 Fed. Reg. at 7716, 7758-59. Under the APA, agencies must acknowledge a change in position and provide a reasoned explanation for that change. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125-26 (2016). They need not—as NFPRHA would have it—address every statement or rationale underpinning the prior policy. HHS acknowledged differences between the 2000 regulations and the Rule and explained the reasons for the change. Nothing more is required by the APA. *See id.* at 2126 (2016).

NFPRHA similarly errs in claiming that HHS "failed to address its abandonment" of Quality Family Planning guidelines, referring to a 2014 publication containing clinical recommendations for providing quality family planning services. NFPRHA MSJ at 15; *see id*. at 13-15, 16. HHS continues to expect Title X providers to follow QFP guidelines to the extent they are consistent with the Rule. To the extent that those guidelines might conflict with the Rule, HHS acknowledged that it was departing from its prior approach under the 2000 regulations, and the QFP guidelines in place at the time of the Rule did not (and indeed could not) substantively go beyond the 2000 regulations. *See, e.g.*, 84 Fed. Reg. at 7715. Moreover, while NFPRHA claims that HHS did not "provide a

reasoned explanation for abandoning" the QFP guidelines, NFPRHA MSJ at 16 n.3, HHS reasonably explained that it was adopting the Rule based on the best reading of § 1008.

Additionally, NFPRHA does not advance its claims by rehashing these very same arguments under the rubric of allegedly imposing additional costs on patients. *Id*. at 18-19. Its real objection is to HHS's policy decision, rather than to whether HHS adequately weighted any such alleged costs. But that decision is, of course, not NFPRHA's to make. As to the actual weighing of costs and benefits, the principle that "a court is not to substitute its judgment for that of the agency" is "especially true when the agency is called upon to weigh the costs and benefits of alternative polic[i]es." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003) (citation omitted). And here, of course, HHS did consider potential costs and benefits to patients, but merely reach and different conclusion than the one Plaintiffs would have preferred. *See* 84 Fed. Reg. at 7745-46.

Second, HHS expressly considered and responded to comments arguing that the Rule would force providers to violate medical ethics. *See* 84 Fed. Reg. at 7724, 7748. As explained previously, *see* Def. MSJ at 34-36, HHS concluded that those concerns were misplaced, relying on federal and state conscience laws permitting providers to take the same actions required by the Rule, and on *Rust*'s upholding a nearly identical, but stricter, version of the referral and counseling restrictions over similar objections. *See* 84 Fed. Reg. at 7742, 7748.

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While NFPRHA disagrees with HHS's conclusion, NFPRHA MSJ at 20-24, it fails to show that that conclusion was unreasonable. NFPRHA attempts to downplay the importance of the conscience statutes, *id*. at 22 n.6, but those laws demonstrate that Congress and state legislatures do not believe that medical ethics require that all medical providers must refer for abortion. Similarly, NFPRHA contends that *Rust* is "inapposite," *id*. at 22, but the Court upheld the restrictions against a First Amendment challenge in the face of a dissent arguing that they compelled doctors to violate medical ethics. Def. MSJ at 35-36. The Court explained that a doctor was "always free to make clear that advice regarding abortion is simply beyond the scope of the program," *Rust*, 500 U.S. at 200, and the same is true under the present Rule, *see* 42 C.F.R. § 59.14(e)(5).

More fundamentally, NFPRHA's grievance is with the limited nature of the Title X program itself. Title X creates a limited program, focused on preconception services, and in that context, the doctor-patient relationship is not "sufficiently all encompassing so as to justify an expectation on the part of the patient of comprehensive medical advice." 500 U.S. at 200. And because Title X "does not provide post conception medical care, . . . a doctor's silence with regard to abortion cannot reasonably be thought to mislead a client into thinking that the doctor does not consider abortion an appropriate option for her." *Id*. Congress's limitations on the program no more violate a physician's ethical responsibilities than her First Amendment rights.

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Third, because HHS reasonably concluded that the referral and counseling restrictions do not force Title X grantees to violate medical ethics, NFPRHA cannot override that reasoned determination by threatening that "the Rule causes provider departures through its distortion of the provider-patient relationship and conflicts with professional norms." NFPRHA MSJ at 24; *see also id*. at 24-27. NFPRHA's assertion that the Rule forces providers to leave Title X depends on its incorrect premise that the Rule requires violations of medical ethics, and NFPRHA cites no authority for the extraordinary proposition that an agency administering a competitive grant program must either accede to the wishes of a subset of current grantees or identify in advance those entities who will take their place. Indeed, similar threats did not alter the outcome in *Rust*, and NFPRHA offers no reason why this case should be different. *See* Planned Parenthood Amicus Brief at 14 n.45, *Rust* (Nos. 89-1391, -1392), 1990 WL 10012649 ("Since many providers will not accept Title X funds under the unethical restrictions imposed by the regulations, they will be forced to close or drastically curtail services, depriving poor women of their sole source of family planning services.").

Regardless, HHS reasonably predicted that any withdrawing incumbent providers likely will be replaced by new providers who were previously discouraged from joining the program by the abortion-referral requirement in the 2000 rule, or who will otherwise be willing to compete for and accept federal funds under the Rule. HHS explained that "under the 2000 regulations, some

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individuals and entities may have chosen not to apply to provide Title X services because they anticipated they would be pressured to counsel or refer for abortions," 84 Fed. Reg. at 7780, and it pointed to data showing that a substantial number of medical professionals would limit the scope of their practice if forced to provide services that violated their conscience, *id*. at 7781 n.139. In addition, HHS had received input from "supportive commenters not[ing] that the 2000 regulations stand in the way of some organizations applying for Title X funds, or participating in Title X projects, due to the requirement for abortion referrals and information." *Id*. at 7744. HHS thus predicted that the Rule may "lead to an increase in the number of health care providers who apply and receive funding under the Title X program, thus decreasing current gaps in family planning services in certain areas of the country." *Id*. at 7780.

As Defendants have explained, those predictions have been borne out, with new providers emerging as a result of the Rule's referral provisions, as evidenced by recent challenges to the abortion-referral requirement in the 2000 regulations brought by current and prospective Title X grantees on the basis of statutory and constitutional protections for religious beliefs. *See* Def. MSJ at 38-39. These subsequent events belie NFPRHA's contention that HHS's prediction was unreasonable. *See* NFPRHA MSJ at 30-33. Although NFPRHA suggests these providers are inadequate substitutes, *id*. at 33-35, HHS was permitted to consider the emergence of new providers regardless of Plaintiffs' subjective evaluations of such providers, and the existence of such lawsuits alone confirms the

reasonableness of HHS's prediction. Indeed, HHS expects the Rule's new application criteria favoring innovative approaches for underserved populations to "encourag[e] broader and more diverse applicants," 84 Fed. Reg. at 7718, a feature HHS found weighs in the Rule's favor. And more generally, HHS explained, it could not precisely "anticipate future turnover in grantees"—which hinges on the decisions of various independent actors—meaning any such "calculations would be purely speculative, and, thus, very difficult to forecast or quantify." *Id*. at 7782. In all events, HHS concluded that "compliance with statutory program integrity provisions is of greater importance" than the "cost" of departing from the status quo, *id*. at 7783, and the APA does not permit courts to second-guess that policy judgment.[6]

Fourth, NFPRHA questions HHS's decision to restrict nondirective pregnancy counseling to physicians and advance practice providers (APPs).

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[6] NFPRHA errs in contending that the APA somehow bars the Court from examining whether subsequent events have borne out HHS's reasonable prediction that the Rule may lead to an increase in the number of Title X providers. NFPRHA MSJ at 35. Neither *Michigan v. EPA*, 135 S. Ct. 2699 (2015), nor *SEC v. Chenery Corp*., 318 U.S. 80 (1943), suggests that a reviewing court may not make such an examination, but only that a reviewing court may not uphold agency action based on a substantive argument that the agency did not invoke when it took the action under review. *See Michigan*, 135 S. Ct. at 2710.

NFPRHA MSJ at 27-29. But HHS sensibly required that those who use federal funds to provide counseling concerning a medical condition (pregnancy) "receive at least a graduate level degree in the relevant medical field and maintain a federal or State-level certification and licensure to diagnose, treat, and *counsel* patients." 84 Fed. Reg. at 7728 (emphasis added).

Finally, NFPRHA invites the Court to second-guess HHS's judgment in weighing the potential benefits of the Rule. NFPRHA MSJ at 29-30. But as explained above, the principle that "a court is not to substitute its judgment for that of the agency" is "especially true when the agency is called upon to weigh the costs and benefits of alternative polic[i]es." *Consumer Elecs. Ass'n*, 347 F.3d at 303 (citation omitted). In any event, NFPRHA incorrectly characterizes HHS's description of the Rule's potential benefits. For example, HHS explained that the Rule "seeks to remedy the potential for confusion, under the 2000 regulations, about whether Title X funds can be, or are being used, in a project where abortion is a method of family planning," *inter alia*, by "improving grant monitoring. . . to prevent the misuse of taxpayer funds." 84 Fed. Reg. at 7725. It is reasonable to anticipate that relieving such confusion will "reduce the regulatory burden associated with monitoring and regulating Title X providers for compliance." *Id.* at 7719.

B. The Separation Requirement Is Reasonable.

Plaintiffs fare no better in arguing that the Rule's physical-separation requirement is arbitrary and capricious.

1. Plaintiffs contend, first, that HHS failed to rationally explain alleged conflicts between the separation requirements and the factual findings on which HHS based the 2000 Rule. *See* NFPRHA MSJ at 36-41. Not so. The 2000 regulations already mandated financial separation, 84 Fed. Reg. at 7715; 65 Fed. Reg. at 41,276, and HHS reasonably determined that physical separation also is warranted to address the risk that taxpayer funds will be used to fund abortion—the same rationale approved in *Rust*.

Plaintiffs disagree with that conclusion, and they point to statements in the preamble to the 2000 regulations that they allege support their position. NFPRHA MSJ at. 36-37. Yet, the Supreme Court held in *Rust* that HHS's predictive judgement about how best to comply with § 1008 was a reasonable basis for the same requirement Plaintiffs challenge here. 500 U.S. at 187. As in *Rust*, HHS justified its policy by explaining that the prior regulations "failed to implement properly the statute." *Id.* And HHS considered and discussed reliance interests, comments received, and the previous approaches, ultimately "reaffirm[ing the] reasoned determination" it made in 1988. 84 Fed. Reg. at 7724. The observation that Title X projects previously used funds "for the critical building blocks . . . such as utilities, staff training, office systems, bulk purchasing, and outreach activities," NFPRHA MSJ at 47 (citing 84 Fed. Reg. at 7773-74), underscores HHS's conclusion that collocation of Title X clinics and abortion clinics has the effect of subsidizing abortion in violation of § 1008. *See id.* at 7766. There is

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therefore no merit to the claim that HHS's 2000 factual findings somehow undermine the current Rule, or that the Rule is otherwise arbitrary and capricious.

Contrary to Plaintiffs' claims, *see* NFPRHA MSJ at 37-41; Wash. MSJ at 16-20, 28-33, Defendants also took into account the relevant reliance interests when promulgating the challenged Rule, as Defendants have already explained at length. *See* Defs.' MSJ at 37; Defs.' PI Opp'n at 42-44. Although Plaintiffs provide a lengthy description of how grantees have operated in the past, and point to various comments expressing a different view than the one the agency adopted, HHS's consideration included all of the points that Plaintiffs now raise in their briefs, and HHS reasonably explained why it was departing from past practice. Similarly, although Washington disputes it, *see* Wash. MSJ at 20-28, HHS also considered the effects on public health and patients, and explained that public health would benefit from the Rule, which would "contribute to more clients being served, gaps in service being closed, and improved client care." 84 Fed. Reg. at 7723. HHS therefore acted lawfully, as affirmed in *Rust*.

Somewhat remarkably, NFPRHA also objects to HHS's encouragement of grantees to contact the relevant program office with any questions regarding how to comply with the separation requirement. *See* NFPRHA MSJ at 42; *see also* 84 Fed. Reg. at 7766 ("The Department encourages grantees to contact the program office with questions, discuss ways to comply with the physical separation requirement, and to put a workable plan in place to meet the compliance deadline."). Yet, it cannot, of course, be arbitrary and capricious for the

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government merely to offer to make itself available to provide additional information in the event compliance questions arise. Plaintiffs also fault HHS for failing to provide further explanation, or so-called "objective guideposts," on what it means to provide "direct implementation" of a Title X project or "direct services" to clients. *See* NFPRHA MSJ at 42-43 (citing § 59.18). There is no ambiguity in those terms, despite Plaintiffs' claim to the contrary. And even if there were, Plaintiffs could seek guidance from HHS on any implementation questions by simply asking, as discussed above. *See Nat'l Family Planning & Reprod. Health Ass'n v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir 2006) ("Here the association has within its grasp an easy means for alleviating the alleged uncertainty. It could inquire of HHS exactly how the agency proposes to resolve any of the conflicts that it claims to spot between the amendment and the regulations.").

The same can be said of NFPRHA's claim that HHS is the "lone arbiter" of compliance. NFPRHA MSJ at 42. As the agency providing federal grant funds, HHS is, of course, tasked with evaluating compliance, and that is unobjectionable. And its compliance decisions are reviewable if Plaintiffs were to challenge them. *See* Defs.' MSJ at 44-45 n.5. But Plaintiffs are incorrect that the Rule and the accompanying preamble do not provide sufficient information to understand what grantees must do to satisfy the physical separation requirement. That requirement is described at great length in the preamble. *See, e.g.* 84 Fed. Reg. at 7774-75. And, again, grantees may contact HHS if there are any potential ambiguities to

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seek clarification. Plaintiffs also claim that the 1988 regulations rejected the requirement that separation extend to "office entrances and exits" as too onerous. *See* NFPRHA MSJ at 41-42 (citing 53 Fed. Reg. at 3938-41). But that is incorrect. In 1988, did not make a determination that separate entrances and exits would be too onerous. Rather, HHS opted to judge whether the physical separation requirement was satisfied "based on a review of facts and circumstances," *see* 53 Fed. Reg. at 2945 (§ 59.9); *see also id*. at 2940-41. Thus, despite NFPRHA's argument that the current Rule lacks sufficient objective standards, the 1988 regulations upheld in *Rust* provided *less* guidance than those that Plaintiffs challenge here. *See* 84 Fed. Reg. at 7789 (§ 59.15) (providing factors relevant to the determination of whether the physical separation requirement is satisfied).

2. Plaintiffs also argue that HHS underestimated compliance costs that the proposed rule may impose, and underestimated—in Plaintiffs' view—the potential withdrawals of Title X grantees from the program and resulting disruption. *See* NFPRHA MSJ at 43-48; Wash. MSJ at 20-28. As Defendants have explained previously, however, HHS, which administers the Title X program, is best situated to consider the potential effects on that program and it expressly did so. *See* 84 Fed. Reg. at 7781-82. Although commenters "provided extremely high cost estimates based on assumptions that they would have to build new facilities" to comply with the physical-separation requirement, HHS reasonably anticipated "that entities will usually choose the lowest cost method to come into compliance," such as "shift[ing] their abortion services" to one of their

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multiple "distinct facilities." *Id.* at 7781. And in any event, HHS "acknowledg[ed] that there is substantial uncertainty regarding the magnitude of the[] effects" of the physical-separation requirement, and provided an "estimate" of "an average" that was "an increase from [the] averaged estimate . . . in the proposed rule." *Id.* at 7781-82. Thus, in considering the compliance costs on providers and the possibility that some incumbent providers might withdraw from the program, HHS simply made a different judgment than plaintiffs, which it of course was permitted to do. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

Plaintiffs rely extensively on comments in the record supporting their position. Yet, nothing in the APA requires an agency to defer to the views of any particular commenter over the agency's own. Rather, the agency must consider significant comments and provide a reasoned response. *See Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015). Having considered the Rule's effects, HHS concluded that the Rule was warranted to comply with Title X notwithstanding those predicted costs and effects. That decision was not irrational simply because plaintiffs disagree with HHS's predictive judgments or ultimate conclusion that the benefits outweighed the costs. *See* Defs.' PI Opp'n at 48-49; Defs.' MSJ at 37-39. Plaintiffs also apparently disagree with HHS's weighing of the effects of the separation requirement on patients, *see* NFPRHA MSJ at 48-53, but HHS clearly considered that issue and explained why patients would not be harmed, *see, e.g.*, 84 Fed. Reg. at 7782. HHS therefore met its obligation to provide a reasoned basis for its decision.

C. The Rule Does Not Arbitrarily Interfere with Title X or Otherwise Interfere with Title X's Purpose.

NFPRHA asserts that various ancillary provisions of the Rule are, in NFPRHA's view, "based on irrational purported reasoning." NFPRHA MSJ at 54. These arguments amount to nothing more than an impermissible attempt to substitute Plaintiffs' views for those of the agency, and the Court should reject them. *See, e.g.*, *Nat'l Wildlife Fed'n v. U.S. Army Corps of Eng'rs*, 384 F.3d 1163, 1180 (9th Cir. 2004) ("Our judicial role is not to second-guess the decisions of the agency, but to determine whether, on the administrative record, the agency's actions were arbitrary and capricious, an abuse of discretion, or contrary to law.").[7]

1. To begin, NFPRHA again challenges 42 C.F.R. § 59.5(a)(12), this time on the ground that it "would block existing or future Title X sites in areas where low-income patients lack access to primary care." NFPRHA MSJ at 55. As explained above, however, the requirement that Title X providers "[s]hould offer either comprehensive primary health services onsite or have a robust referral linkage with primary health care providers who are in close physical proximity" reasonably encourages access to primary health care services and supports other health care goals without limiting access to care. *See* 84 Fed. Reg. at 7725. And

[7] NFPRHA also quibbles with minor aspects of the Rule's definitional section, 42 C.F.R. § 59.2. *see* NFPRHA MSJ at 66-68, but provides no basis on which to set aside the Secretary's judgment under the APA's lenient standard.

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to the extent NFPRHA's concern is confusion, Title X applicants can always seek clarity from HHS. *See id*. at 7766 ("The Department welcomes regular interaction with grantees and subrecipients, should they have questions. Project officers are available to help grantees successfully implement the Title X program in compliance with both the statute and the regulation.").[8]

NFPRHA's concerns are further unfounded because § 59.5(a)(12) does not impose an absolute requirement that a project offer either comprehensive primary health services onsite or have linkages to primary health providers in close proximity. *See* 42 C.F.R. § 59.5(a)(12). It instead reflects Congress's expectation that "Family Planning Services under Title X generally are most effectively provided in a general health setting." 84 Fed. Reg. at 7749 (quoting S. Rep. No. 63, 94 Cong., 1st Sess. 65-66 (1975)). HHS also accounts for the geographic distribution of services when making grant decisions. *See* Announcement of

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[8] Plaintiffs also puzzlingly suggest that this requirement is "inconsistent with" the physical separation requirement. NFPRHA MSJ at 56-57. To the extent the comprehensive primary health services are located onsite at a Title X project, any services must, of course, be kept separate from the abortion-related activities that the Rule prohibits.

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Availability of Funds for Title X Family Planning Services Grants, Notice at 49-50.[9]

2. Next, NFPRHA contends that the Rule will degrade care because it removes the requirement that a Title X project provide "medically approved" family planning methods and allows entities to offer only a single method or a limited number of family planning methods. NFPRHA MSJ at 57-59. But HHS addressed these concerns by explaining that, even if individual service sites might offer a limited number of family planning methods, each Title X project, as a whole, must "provide[] a broad range of family planning methods and services, including contraception and natural family planning." 84 Fed. Reg. at 7732; *see also* 42 C.F.R. § 59.5(a)(1) ("A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.").

And with regard to the removal of the "medically approved" requirement in particular, NFPRHA's complaint is with Congress, not HHS: "When Congress specified what family planning methods and services Title X projects must provide, Congress directed that the methods and services be 'acceptable and effective'; it did not specify that they be 'medically approved.'" 84 Fed. Reg. at 7732 (quoting 42 U.S.C. § 300(a)). HHS addressed this issue directly, *see id*. at

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[9] https://www.hhs.gov/opa/sites/default/files/FY2019-FOA-FP-services-amended.pdf.

7732, 7740-41, and explained that the "medically approved" language had not proved useful in practice, *see id*. at 7732 (explaining the practical difficulty of enforcing the "medically approved" requirement). This response was an adequate justification for returning to the text of the statute, which requires that any family planning services be "acceptable and effective," and which HHS rationally concluded would "sufficiently ensure[]" that Title X clients receive appropriate services. *Id*.[10]

3. NFPRHA also objects to certain changes that the Rule made to the Title X "grant-making criteria." *See* NFPRHA at 60-65. In particular, it challenges the Rule's requirement that Title X grant applicants demonstrate their "affirmative compliance" with the other, substantive requirements of the Rule. *See* 42 C.F.R. § 59.7(b). As HHS explained, however, it implemented this additional requirement "to better direct Title X funds for family planning projects, to prevent misuse of funds, and to save taxpayer dollars by only sending qualified

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[10] NFPRHA also is in no position to object that *other* providers might offer family planning methods and services that NFPRHA would not itself offer. *See, e.g.*, NFPRHA MSJ at 58. The Rule leaves NFPRHA free to decide which methods and services to offer so long as its project grantees meet the statutory and regulatory requirements—primarily, that each project offer a broad range of methods (including natural family planning and, as the Rule specifies, contraception).

applications to the costly and time consuming competitive review committee." 84 Fed. Reg. at 7754.

The Court should reject NFPRHA's attempt to Monday-morning quarterback HHS's reasoned judgment regarding the criteria with which to judge applicants for federal funds. Section 1006 of the Title X statute specifically provides that the Secretary may issue regulations setting forth criteria by which HHS will award Title X grants and contracts. 42 U.S.C. § 300a-4(a). HHS's criteria tracks the statute itself, listing and elaborating on the non-exclusive criteria that Congress provided. 42 C.F.R § 59.7(c)(1)-(4). Both the statute and Rule specify that projects shall provide a broad range of family planning methods and services, and that the relative needs of applicants, the capacity to make rapid and effective use of funds, the number of patients to be served, and local need shall be considered when selecting grants. The Rule also provides that proposals must specify how an applicant may meet these and other requirements of the regulations. Title X's grant application process—both before the Rule and under it—is a sophisticated one, with funding announcements and grant applications running many pages long, and subject to a detailed review and scoring system. None of that complexity is new in this Rule, and the preamble to the Rule as well as longstanding agency practice makes it clear that HHS provides applicants with ample guidance during the process.

Additionally, NFPRHA takes issue with new review criteria regarding a grantee's "ability to procure a broad range of diverse subrecipients." NFPRHA

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MSJ at 63 (quoting 84 Fed. Reg. at 7754). But it is eminently reasonable for HHS to ask grantees to show how they can expand the impact of federal funds, consistent with Title X's mandate to provide "a broad range of acceptable and effective family planning methods and services," 42 U.S.C. § 300(a), and to take into account an applicant's capacity to make rapid and effective use of grants and contracts, *id*. § 300(b). NFPRHA's claim to the contrary is meritless.

4. For the reasons discussed above, as well as in Defendants' prior briefing, there is also no merit to NFPRHA's claims that the Rule results from "arbitrary balancing" and "undermines Title X's fundamental purpose." NFPRHA MSJ at 68-72. Unable to show that other portions of the Rule are arbitrary and capricious, NFPRHA finally quibbles with the Rule's requirements for additional information in grant applications and periodic reporting. *See* NFPRHA MSJ at 69-70 (citing § 59.5(a)(13)). However, HHS specifically addressed the concern of additional "administrative burden" that NFPRHA cites, and explained that it was reasonable to promote additional transparency regarding the use of federal funds. *See* 84 Fed. Reg. at 7750. Similarly, HHS also addressed NFPRHA's objections to the additional protections in § 59.17 to rule out victimization of minors. *See* NFPRHA MSJ at 71; *see also* 84 Fed. Reg. 7717, 7771. HHS acknowledged that complying with State and local laws may be complicated and reasonably required grantees to have measures in place to ensure

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compliance and to strengthen protections for minors. *See* Fed. Reg. at 7771.[11] These common sense compliance requirements in the Rule cannot render it arbitrary and capricious.

III. PLAINTIFFS' LOGICAL OUTGROWTH CLAIM IS MERITLESS

Although Plaintiffs claim that certain of the Rule's provisions do not constitute the logical outgrowths of HHS's proposals in the NPRM, Wash. MSJ at 34-39, a "final regulation that varies from the proposal, even substantially, will be valid as long as it is 'in character with the original proposal and a logical outgrowth of the notice and comments.'" *Hodge v. Dalton*, 107 F.3d 705, 712 (9th Cir. 1997) (citation omitted). To determine whether notice was adequate, courts ask whether a complaining party should have anticipated that a particular requirement might be imposed, and whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule. *Envt'l Def. Ctr. v. EPA*, 344 F.3d 832, 851 (9th Cir. 2003). Plaintiffs received sufficient notice under this standard.

First, it is irrelevant that the proposed rule did not specifically seek comment on whether referrals for prenatal care were medically necessary for all

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[11] NFPRHA also refers to § 59.18(c) as "counterproductive," but does not explain its reasoning for that conclusion. That portion of the Rule merely requires grantees to account for their charges against Title X grants, and is unobjectionable. *See* 84 Fed. Reg. at 7791 (§ 59.18(c)).

pregnant patients, Wash. MSJ at 35-36, because the final rule does not depend on HHS's "pronouncement" that such referrals are medically necessary as the basis for any substantive component. The final rule (and the NPRM) require prenatal referral after pregnancy is established because such a referral aligns with HHS's interpretation of Title X as a pre-conceptional program. The NPRM specifically cites a 1970 House Report to support the proposition that HHS is "clarifying that pregnant women *must be referred* for appropriate prenatal care services, rather than receiving them within a Title X project, because those services are not part of family planning services within the Title X program." 83 Fed. Reg. at 25502, 25505 (citing H.R. Rep. No. 91-1472 (1970) (emphasis added)). The NPRM also clearly states: "Title X projects do not themselves provide post-conception care. Thus, proposed § 59.14 *would require that pregnant women be referred* outside of the Title X project for prenatal care and other related medical and social services, as well as for other services relating to pregnancy after pregnancy is confirmed." *Id*. at 25,518 (emphasis added). Accordingly, the final rule states that "once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care." 84 Fed. Reg. at 7789. In other words, the use of the phrase "medically necessary" in the final rule does not change the referral requirement from the NPRM to the final rule: the underlying requirement does not depend on a finding of medical necessity but on HHS's interpretation of *Rust*. Under both the NPRM and the

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final rule, pregnant clients are to be referred for prenatal health care because "Title X is limited to preconceptional services." *Rust*, 500 U.S. at 179.

Second, HHS could not have been clearer in the proposed rule that under Section 59.14(b)(1)(ii), the list provided to patients would include only "comprehensive health service providers." *See* 83 Fed. Reg. at 25,531. Plaintiffs appear to object that the language in the proposed rule did not specify that "comprehensive health care service providers" must also provide primary care services. Wash. MSJ at 37. But "comprehensive" means just that—"comprehensive" care, which necessarily includes primary care services. And commenters raised precisely the same concern that Plaintiffs flag—that the restrictions on what type of providers may be included in the list will "diminish[] the ability to include any abortion providers on the list." *Id*. As HHS described in the preamble, "many commenters oppose the list of providers that may be shared with pregnant patients who request abortion" because they "believe the list . . . may be . . . difficult to implement for some providers because of the lack of comprehensive service providers who also provide abortion in their community." 84 Fed. Reg. at 7760. Thus, not only were commenters on notice of this aspect of the Rule, they offered their views on the subject.

Third, Plaintiffs fail to show that HHS's replacement of the phrase "medically indicated" with the phrase "medically necessary" in Section 59.5(b)(1) of the final rule makes any material difference. Wash. MSJ at 37-38. The final rule makes clear that this change was made for stylistic purposes: "The proposed

rule would amend § 59.5(b)(1) to require that any referrals to other medical facilities be made consistent with § 59.14(a), which would bar referral for abortion as a method of family planning. The department finalizes 42 CFR 59.5(b)(1) with stylistic changes and to change the phrase 'when medically indicated' to 'when medically necessary.'" 84 Fed. Reg. at 7752. Referrals for abortion as a method of family planning are prohibited in both the NPRM and in the final rule because referrals must be "consistent with § 59.14(a)." 83 Fed. Reg. at 25,530; 84 Fed. Reg. at 7752. The bulk of Plaintiffs' argument conflates the use of the phrase "medically necessary" with a restriction on providers' abilities to refer that simply does not exist, except with respect to abortion. Wash. MSJ at 37-38. But Plaintiffs fail to explain how the substitution of the phrase "medically necessary" in the final rule for stylistic reasons makes any substantive difference. Notice and comment was therefore not required for HHS to implement this change in word choice.

Finally, Plaintiffs incorrectly claim the NPRM provided no notice with respect to the requirement that nondirective pregnancy counseling come from physicians or "advanced practice providers." *Id*. at 38-39. Under the governing standard, Plaintiffs received sufficient notice, as the question of which types of providers and/or staff may engage with and provide information to patients was squarely presented. Indeed, HHS initially proposed to allow only physicians to provide nondirective counseling, *see* 83 Fed. Reg. at 25,531; 25,507; 25,518, but, in response to comments, decided to allow both physicians and APPs to offer nondirective counseling, 84 Fed. Reg. at 7761. Because this question was

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presented, and HHS adopted a less restrictive approach in response to comments, Plaintiffs' notice-and-comment claim is meritless. Indeed, a district court in a related challenge to the Rule rejected a materially indistinguishable logical-outgrowth challenge to the same provision. *See California v. Azar*, 385 F. Supp. 3d 960, 1020-21 (N.D. Cal. 2019).

IV. PLAINTIFFS' CONSTITUTIONAL CLAIMS ARE MERITLESS

As explained in Defendants' opening brief, Plaintiffs' constitutional claims fail in light of *Rust*. *See* Defs.' MSJ at 42-46. Plaintiffs do not seriously contest Defendants' arguments, instead contending that the Court need not reach Plaintiffs' constitutional claims because alleged "statutory violations are so pervasive." NFPRHA MSJ at 75; Wash. MSJ at 70. As argued above, that is not the case. And to the extent Washington does attempt to justify its constitutional claims, its arguments are meritless.

A. The Rule Does Not Violate the First Amendment

Although Plaintiffs do not dispute that *Rust* remains good law, they contend that the decision "left open" the question of whether "traditional relationships such as that between doctor and patient should enjoy protection under the First Amendment in the context of a government-subsidized health care program." Wash. MSJ at 70. But as Plaintiffs cannot help but acknowledge, the Supreme Court nonetheless rejected the First Amendment challenge because the 1988 "regulations do not significantly impinge upon the doctor-patient relationship." *Rust*, 500 U.S. at 200. Plaintiffs suggest that the nondirective provision has

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fundamentally altered the nature of the Title X program, such that what was true in 1988—*i.e.*, that "the doctor-patient relationship established by the Title X program [is not] sufficiently all encompassing so as to justify an expectation on the part of the patient of comprehensive medical advice" and that "a doctor's silence with regard to abortion cannot reasonably be thought to mislead a client into thinking that the doctor does not consider abortion an appropriate option for her," *id.*—is no longer true today. *See* Wash. MSJ at 70-71. But Plaintiffs again vastly overstate the importance of the appropriations rider and its impact on the Title X program, which remains fundamentally the same today as it was when *Rust* held that substantially similar regulations did not violate the First Amendment. Accordingly, as in *Rust*, "the general rule that the Government may choose not to subsidize speech applies with full force." *Rust*, 500 U.S. at 200.

Plaintiffs attempt to rely on the Supreme Court's recent decision in *National Institute of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*) to undermine the applicability of *Rust* to this case. *See* Wash. MSJ at 70-71. That decision, however, did not address government *subsidization* of speech at all, but a law purporting to *compel* certain pregnancy clinics to provide particular notices. *See* 138 S. Ct. at 2368-78. It did not even mention *Rust*, which is unsurprising given the settled rule that, as a general matter, "if a party objects to a condition on the receipt of federal funding, its recourse is to decline the funds," even "when the objection is that a condition may affect the recipient's exercise of its First Amendment rights." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*

(*AOSI*), 570 U.S. 205, 214 (2013) (collecting cases). In any event, even if *NIFLA* could somehow be read as calling *Rust* into question—which it cannot—*Rust* would still be binding here. *See Rodriquez de Quijas v. Shearson/Am. Exp., Inc.*, 490 U.S. 477, 484 (1989) ("If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the [lower court] should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.").

Plaintiffs also contend that the Rule "interferes with Title X recipients' activities outside the Title X program." Wash. MSJ at 71. Plaintiffs do not explain, however, how the Rule differs from the 1988 regulations, which the Supreme Court upheld against an unconstitutional conditions challenge after concluding that the regulations "govern the scope of the Title X *project*'s activities, and leave the grantee unfettered in its other activities." *Rust*, 500 U.S. at 196-97. Thus, *Rust* controls this argument, and *AOSI*, which explicitly reaffirmed *Rust*, is not to the contrary, as Plaintiffs suggest, Wash. MSJ at 71-72.

B. The Rule Is Not Unconstitutionally Vague

Nor is the Rule unconstitutionally vague, for the reasons explained in Defendants' opening brief. *See* Defs. MSJ at 43-45. Plaintiffs do not respond to Defendants' arguments, other than to contend that 42 C.F.R. § 59.7(b), apparently by itself, "presents independent constitutional issues." Wash. MSJ at 72-73. What Plaintiffs challenge, though, is the conditions that provision sets forth for the Secretary's review of applications for discretionary agency grants. They

ignore the fundamental point, as Defendants have explained, that this case arises in "the context of selective subsidies" rather than an exercise of the government's coercive regulatory authority. *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 589 (1998). As such, the "consequences of imprecision are not constitutionally severe." *Id.*

In any event, Plaintiffs' vagueness challenge to the purported "all-encompassing, uncertain eligibility" requirement, Wash. MSJ at 72, is meritless because that provision merely requires that entities address, in their applications, how they intend to "satisfy the requirements" of the Rule, which requirements are not themselves vague. The separation requirements based on a review of all the facts and circumstances are the same as those set forth in the 1988 regulations (and upheld in *Rust*) and the Rule elsewhere provides extensive guidance regarding compliance with the Rule's counseling provisions. *See, e.g.*, 84 Fed. Reg. at 7747 (offering "guidance on the requirement of nondirective pregnancy counseling"); 42 C.F.R. § 59.16(b) (providing eight examples to illustrate what is permissible and what is prohibited with respect to counseling). The Rule is not unconstitutionally vague.

V. THE COURT SHOULD AWAIT GUIDANCE ON THE MERITS FROM THE NINTH CIRCUIT

Defendants are entitled to judgment in their favor, and Plaintiffs' motion should be denied, for the reasons explained above and in Defendants' prior briefs. However, even if there were any doubt, or if the Court were to believe that

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Plaintiffs' arguments have merit, the Court should await guidance from the Ninth Circuit before ruling.

As the Court is aware, a motions panel of the Ninth Circuit issued a unanimous per curiam order on June 20, 2019 staying this Court's preliminary injunction—along with the two other injunction issued by district courts in Oregon and California—pending appeal. *See California v. Azar*, 927 F.3d 1068 (9th Cir. 2019). It concluded that HHS is likely to prevail on the merits and that the equitable factors cut in the Department's favor. *Id.* at 1075-80. The panel emphasized that the Rule is "reasonable and in accord with § 1008," as confirmed by *Rust*. *Id.* at 1075. It also concluded that Plaintiffs are unlikely to succeed on their claim that the Rule is arbitrary and capricious. *Id.*at 1079-80.

Plaintiffs moved for *en banc* reconsideration of the panel's stay order, which was granted. *See Washington v. Azar*, No. 19-35394, Order (July 3, 2019). The *en banc* panel of the Ninth Circuit initially ordered that the motions panel decision not be cited as precedent, *id*., but later clarified that the panel's stay order had not been vacated and denied the Plaintiffs' motions for an administrative stay of the stay order, *Washington v. Azar*, No. 19-35394, Order (July 11, 2019). The *en banc* panel then scheduled oral argument and instructed the parties to "be prepared to discuss . . . the district courts' preliminary injunction orders on the merits." *Washington v. Azar*, No. 19-35394, Order (Aug. 1, 2019). The panel heard argument on September 23, 2019, which addressed the merits of the preliminary injunction orders.

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The forthcoming ruling from the *en banc* Ninth Circuit is likely to provide substantial, if not dispositive, guidance to this Court and the parties in resolving the central merits issues of this case. For that reason, the district courts in California and Oregon have indicated that they will await the Ninth Circuit's ruling before further addressing the merits in the parallel litigation. The Oregon district court granted a stay of proceedings on September 17, 2019, observing that "it is hard to imagine that the [Ninth Circuit's] decision on appeal would not guide this court robustly." *Oregon v. Azar*, No. 6:19-cv-00317-MC, Opinion and Order at 5, ECF No. 191 (D. Or. Sept. 17, 2019). On October 2, 2019, the California district court similarly stayed Defendants' motion to dismiss "given the pendency of the appeal before the Ninth Circuit." *California v. Azar*, No. 3:19-cv-01184-EMC, Clerk's Notice, ECF No. 151 (N.D. Cal. Oct. 1, 2019).

Defendants respectfully submit that this Court should await the Ninth Circuit's guidance before ruling on the parties' current dispositive motions. At a minimum, if the Court does issue a ruling in Plaintiffs' favor, Defendants ask that the Court stay the effect of its order pending appeal to avoid the need for Defendants to consider seeking emergency appellate relief.

CONCLUSION

For the foregoing reasons, and those set forth in their opening brief, Defendants respectfully request that the Court grant Defendants' motion to

dismiss or, in the alternative, for summary judgment; deny Plaintiffs' motions for summary judgment; and enter summary judgment in Defendants' favor.[12]

Dated: January 10, 2020

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[12] If the Court ultimately disagrees with Defendants and decides to award Plaintiffs summary judgment with respect to any of their claims, the scope of relief should be limited. Defendants dispute that the extreme remedy of vacatur is proper in this case, *see* NFPRHA MSJ at 75, and submit, as they have previously argued, that any remedial order (vacatur included) should be no broader than necessary to provide Plaintiffs relief, and should therefore extend only to the Plaintiffs and only to the specific provisions of the Rule that the Court finds unlawful. *See* Defs.' PI Opp'n at 60-66.

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